

**An Extended F<sub>1</sub>-Generation Reproductive Toxicity Evaluation  
of Patched BIOCELL® INTRASHIEL® Shell of Gel-Filled Breast Implants in  
Sprague Dawley Rats**

**CONCLUSION**

Additional animal testing associated with an "extended F<sub>1</sub>-generation" evaluation has been provided to address the reproductive toxicity and teratogenicity testing requirement for the patched silicone-filled breast implant shell. The reproductive competency in both the F<sub>0</sub>-generation and F<sub>1</sub>-generation and the normalcy of the F<sub>2</sub>-litters indicates of a lack of reproductive toxicity associated with the *in utero* exposure to patched silicone-filled breast implant shells.